

AMENDMENTS TO THE CLAIMS

1. (currently amended) A sustained release oral pharmaceutical dosage formulation comprising:

(a) a core ~~comprising~~ consisting of :

- (i) oxycodone or a pharmaceutically acceptable salt thereof;
- (ii) ~~at least one pharmaceutical excipient~~ a diluent;
- (iii) a binder that is water soluble and has a viscosity of greater than 50,000 mPa when tested in a 2% aqueous solution at 20 °C;
- (iv) optionally a glidant;
- (v) optionally a lubricant; and

(b) a single delayed release coating surrounding the core consisting essentially of:

- (i) about 30 to about 80 weight percent of the delayed release coating of a pH dependent material, wherein the pH dependent material consists of a first enteric coating that begins to dissolve or degrade at a pH of about 5 to about 7 and a second enteric agent that begins to dissolve or degrade at a pH of above 7;
- (ii) about 20 to about 70 weight percent of the delayed release coating of an inert processing aid and;
- (iii) optionally a plasticizer; and

(c) an immediate release drug layer comprising:

- (i) oxycodone or a pharmaceutically acceptable salt thereof;
- (ii) a binder; and

(d) optionally a cosmetic coating

~~wherein the pH dependent material consists of a first enteric coating that begins to dissolve or degrade at a pH of about 5 to about 7 and a second enteric agent that begins to dissolve or degrade at a pH of above 7.~~

2. (canceled).

3. (canceled).

4. (canceled).

5. (canceled).

6. (canceled).

7. (currently amended) The sustained release dosage formulation as defined in claim ~~[[5]]~~ 1 wherein the binder is an osmopolymer.

8. (currently amended) The sustained release dosage formulation as defined in claim ~~[[5]]~~ 1 wherein the binder is water soluble and has a viscosity of greater than 50,000 mPa when tested in a 2% aqueous solution at 20 °C .

9. (currently amended) The sustained release dosage formulation as defined in claim

[[5]] 1 wherein the binder is water soluble and has a viscosity of greater than 75,000 mPa when tested in a 2% aqueous solution at 20 °C .

10. (previously presented) The sustained release dosage formulation as defined in claim 1 wherein the first enteric coating agent begins to dissolve or degrade at a pH of about 5 to about 6 and the second enteric agent begins to dissolve or degrade at a pH of above 7 or is degraded in the gastrointestinal tract.

11. (previously presented) The sustained release dosage formulation as defined in claim 1 wherein the first enteric coating agent begins to dissolve or degrade at a pH of about 6 to about 7 and the second enteric agent begins to dissolve or degrade at a pH of above 8 or is degraded in the gastrointestinal tract.

12. (previously presented) The sustained release dosage formulation as defined in claim 10 wherein the second enteric agent begins to dissolve or degrade at a pH of about 11 to about a pH of 12.

13. (original) The sustained release dosage formulation as defined in claim 10 wherein the ratio of first enteric agent to the second enteric agent is about 1:5 to 5:1.

14. (original) The sustained release dosage formulation as defined in claim 13 wherein the ratio of first enteric agent to the second enteric agent is about 1:2 to about 1:4.

15. (previously presented) The sustained release dosage formulation as defined in claim 1 wherein the pH dependent material comprises about 35 to about 60 percent of the total weight of the delayed release coating.

16. (original) The sustained release dosage formulation as defined in claim 15 wherein the inert processing aid comprises about 30 to about 60 percent of the total weight of the delayed release coating.

17. (currently amended) A sustained release oral pharmaceutical dosage formulation comprising:

(a) a core ~~comprising~~ consisting of:

(i) oxycodone or a pharmaceutically acceptable salt thereof;

(ii) a diluent;

(iii) a binder that is water soluble and has a viscosity of greater than 50,000 mPa when tested in a 2% aqueous solution at 20 °C ;

(iv) optionally a glidant;

(v) optionally a lubricant; and

(b) a single delayed release coating surrounding the core consisting essentially of:

(i) about 35 to about 60 weight percent based upon the total weight of the delayed release coating of a pH dependent material, wherein the pH dependent material consists of a first enteric coating that begins to

dissolve or degrade at a pH of about 5 to about 7 and a second enteric

agent begins to dissolve or degrade at a pH of above 8;

(ii) about 30 to about 60 weight percent of an inert processing aid;

(iii) about 0.1 to about 15 weight percent based upon the total weight of the delayed release coating of a plasticizer; and

(c) an immediate release drug layer comprising:

(i) oxycodone or a pharmaceutically acceptable salt thereof;

(ii) a binder; and

(d) optionally a cosmetic coating ~~wherein the pH dependent material consists of a first enteric coating that begins to dissolve or degrade at a pH of about 5 to about 7 and a second enteric agent begins to dissolve or degrade at a pH of above 8.~~

18. (canceled).

19. (canceled).

20. (previously presented) The sustained release dosage formulation as defined in claim 17 wherein the binder in the core has a viscosity of greater than 75,000 mPa when tested in a 2% aqueous solution at 20 °C.

21. (previously presented) The sustained release dosage formulation as defined in claim 17 wherein the first enteric coating agent begins to dissolve or degrade at a pH of about 6 to about 7 and the second enteric agent begins to dissolve or

degrade at a pH of above 9.

22. (previously presented) The sustained release dosage formulation as defined in claim 17 wherein the second enteric agent begins to dissolve or degrade at a pH of about 11 to about a pH of 12.

23. (original) The sustained release dosage formulation as defined in claim 17 wherein the ratio of first enteric agent to the second enteric agent is about 1:5 to 5:1.

24. (original) The sustained release dosage formulation as defined in claim 17 wherein the ratio of first enteric agent to the second enteric agent is about 1:2 to about 1:4.

25-33. (canceled).